

A

dc922 U.S. PRO
09/703269



10/31/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Robert J. Sweeney et al.

Title: CURVATURE BASED METHOD FOR SELECTING FEATURES FROM AN
ELECTROPHYSIOLOGIC SIGNALS FOR PURPOSE OF COMPLEX IDENTIFICATION AND
CLASSIFICATION

Attorney Docket No.: 279.188US1

PATENT APPLICATION TRANSMITTAL

BOX PATENT APPLICATION

Commissioner for Patents
Washington, D.C. 20231

We are transmitting herewith the following attached items and information (as indicated with an "X"):

Return postcard.

Utility Patent Application under 37 CFR § 1.53(b) comprising:

X Specification (23 pgs, including claims numbered 1 through 40 and a 1 page Abstract).

X Formal Drawing(s) (4 sheets).

X Unsigned Combined Declaration and Power of Attorney (3 pgs).

The filing fee (NOT ENCLOSED) will be calculated as follows:

	No. Filed	No. Extra	Rate	Fee
TOTAL CLAIMS	40 - 20 =	20	x 18 =	\$360.00
INDEPENDENT CLAIMS	2 - 3 =	0	x 80 =	\$0.00
[] MULTIPLE DEPENDENT CLAIMS PRESENTED				\$0.00
BASIC FEE				\$710.00
TOTAL				\$1,070.00

THE FILING FEE WILL BE PAID UPON RECEIPT OF THE NOTICE TO FILE MISSING PARTS.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938, Minneapolis, MN 55402 (612-373-6900)

By: Timothy E. Bianchi
Atty: Timothy E. Bianchi
Reg. No. 39,610

Customer Number 21186

"Express Mail" mailing label number: EL709304003US

Date of Deposit: October 31, 2000

This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to the Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

UNITED STATES PATENT APPLICATION

**CURVATURE BASED METHOD FOR SELECTING
FEATURES FROM AN ELECTROPHYSIOLOGIC SIGNALS
FOR PURPOSE OF COMPLEX IDENTIFICATION
AND CLASSIFICATION**

INVENTORS

ROBERT J. SWEENEY
of Woodbury, MN
ERIC G. LOVETT
of Roseville, MN

Prakash Nama:

Reg. No. 44,255

Schwegman, Lundberg, Woessner, & Kluth, P.A.

1600 TCF Tower

121 South Eighth Street

Minneapolis, Minnesota 55402

ATTORNEY DOCKET NO. 279.188US1

09703269 403400
DOCKET "6950450"

CURVATURE BASED METHOD FOR SELECTING FEATURES FROM AN ELCTROPHYSIOLOGIC SIGNALS FOR PURPOSE OF COMPLEX IDENTIFICATION AND CLASSIFICATION

5 The present invention relates generally to cardiac rhythm management systems, and more particularly, it pertains to a system and method of classification and detection of cardiac signals.

Background of the Invention

10 Analysis of cardiac signals, which is routinely performed in electrocardiography is generally based on visual inspection to quantify or qualify wave morphology for the purpose of identifying and classifying abnormal patterns. Certain morphological characteristics of commonly recorded signals have high diagnostic value. The shape and inter arrival times of R-waves recorded in the electrocardiogram generally provide a
15 wealth of information about the state of the heart. Accordingly, automated approaches for identifying and classifying abnormalities in signals such as cardiac signals have sought to use a signal's significant morphologic characteristics.

 However, given the wide diversity of possible shapes for cardiac signals, it is usually not possible for an automatic approach to identify significant characteristics that
20 can be used for unambiguous classification. Rather, automated classification approaches generally compare the entire morphological shape of a signal with the shape of similar signals with known abnormalities but without particular regard to the specific characteristics that the signals contain. Alternatively, automated classification approaches restrict the automated examination only to those signals which are
25 essentially normal and use detailed metrics (for example QRS width, QT interval or ST segment amplitude) of the essentially normal morphology for classifying abnormalities.

 Despite its importance in the analysis of biologic signals, the automated and accurate identification and quantification of the significant morphological characteristics (for example turns, peaks, knees, inflection points, and the like) in any
30 cardiac signal (both abnormal as well as normal) is still in a developing stage. Existing methods have used the concept of sharpness (for example to detect R-waves) but have

had limited success. This is due in part to the overly simplistic mathematical treatment this concept has received, as reflected in the rudimentary algorithms used for these measurements. Most of the current detection methods rely on three point interpolations to measure sharpness. The simplest and most commonly used methods for measuring peaks of R-waves are based upon Taylor-series approximations to estimate the second derivative of the sensed signal. This formula utilizes highly local information (the point at the peak and its two close neighbors) ignoring nearby points which may contribute to signal peak. Other popular approaches utilize less local data, such as the peak and two adjacent extrema. All of these methods, which rely on three-point estimates of sharpness, may produce inaccurate estimates, if waveforms are complex or are contaminated with noise. Thus, a need exists for automated identification and classification of peaks, knees, inflection points, and the like in sensed cardiac signals that takes into account wave scale and complexity that can yield a more accurate estimate of peaks for identifying and classifying abnormalities in cardiac signals.

Summary of the Invention

The present subject matter provides a curvature based method of selecting features from electrophysiologic signals for purpose of complex identification and classification. According to one aspect of the present subject matter, this is accomplished by sensing a cardiac signal (sensing the cardiac signal includes sensing complexes continuously on a real-time basis) and computing curvatures on a sample point-by-sample point basis ($X_1, X_2, X_3, \dots, X_I$) on the sensed cardiac signal on a continuous basis. In one embodiment, the curvature at the sample points $X_1, X_2, X_3, \dots, X_I$ are computed by fitting a cubic least square error curve (using N number of sample points) to the sensed cardiac signal. In this embodiment, N is an odd number, and the sample point (where the curvature is computed) is at a mid point of the N number of sample points.

Also on a continuous basis, features of significant interest are extracted from the computed curvatures. In some embodiments, this is accomplished by comparing the computed curvatures at the sample points $X_1, X_2, X_3, \dots, X_I$ to a set of predetermined

threshold values. In some embodiments, the features are extracted based on computing features such as a time when the feature occurs, an amplitude of the feature, and other similar features at each of the sample points and comparing them to a set of threshold values.

5 Also on a continuous basis a set of features associated with a first complex in the sensed cardiac signal are identified and separated from the continuously computed and extracted features upon detecting a second subsequent complex. The second subsequent complex is a complex that is adjacent to the first complex and occurs substantially immediately after the first complex. This process of identifying and separating extracted
10 features repeats itself from one sensed complex to another subsequent sensed complex on a real time basis. One reason for identifying and separating the set of features associated with the first complex is to prevent the features associated with the first complex from mixing with the features associated the second subsequent complex. Separating the features associated with first complex aids in classifying the sensed first
15 complex.

Next, the process includes identifying a fiducial feature from the separated set of extracted features associated with the first complex and aligning the separated set of features with respect to the identified fiducial feature. In one embodiment, fiducial feature is identified based on comparing the times when each of the separated set of
20 features occur with a time when a complex associated with the separated set of features is detected on the sensed cardiac signal, and selecting a feature from the separated set of features that is closest in time to the time when the complex associated with the separated set of features was detected. One reason for using a time when a complex is detected (such as R wave) in identifying the fiducial feature, is because the detection of
25 a complex in a sensed cardiac signal is generally more reliable and consistent.

Next, the process includes aligning the separated set of features around the identified fiducial feature. Aligning the separated set of features around the identified fiducial feature aids in normalizing each of the separated set of feature around a datum such as the associated detected complex, and further aids in comparing the separated set
30 of features with a set of predetermined templates.

Next the process includes comparing the aligned set of features to a set of predetermined templates to classify the associated complex. In some embodiments, the predetermined templates are a set of identified complexes associated with known cardiac arrhythmias that would assist in comparing and classifying the extracted set of features. In some embodiments, a therapy is provided to the heart based on the outcome of the classification. The above described process repeats itself on a continuous basis for a real-time classification of complexes from the sensed cardiac signal.

Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

Brief Description of the Drawings

Figure 1 is a cardiac signal according to one aspect of the present invention.

Figure 2 is a curvature figure derived from the cardiac signal of Figure 1 according to one aspect of the present invention.

Figures 3A and 3B illustrate separating and aligning features derived from the curvature figure of Figure 2 according to one aspect of the present invention.

Figure 4. is a flow diagram illustrating generally one embodiment of operation of the present subject matter.

Figure 5 is a schematic/block diagram illustrating generally one embodiment of portions of a cardiac rhythm management system of the present subject matter.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is,

therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

Analysis of cardiac signals, which is routinely performed in electrocardiography is generally based on visual inspection to quantify or qualify wave morphology for the purpose of identifying and classifying abnormal patterns. Certain morphological characteristics of commonly recorded signals have high diagnostic value. The shape and inter arrival times of R-waves recorded in the electrocardiogram generally provide a wealth of information about the state of the heart. Accordingly, automated approaches for identifying and classifying abnormalities in signals such as cardiac signals have sought to use a signal's significant morphologic characteristics.

However, given the wide diversity of possible shapes for cardiac signals, it is usually not possible for an automatic approach to identify significant characteristics that can be used for unambiguous classification. Rather, automated classification approaches generally compare the entire morphological shape of a signal with the shape of similar signals with known abnormalities but without particular regard to the specific characteristics that the signals contain. Alternatively, automated classification approaches restrict the automated examination only to those signals which are essentially normal and use detailed metrics (for example QRS width, QT interval or ST segment amplitude) of the essentially normal morphology for classifying abnormalities.

Despite its importance in the analysis of biologic signals, the automated and accurate identification and quantification of the significant morphological characteristics (for example turns, peaks, knees, inflection points, and the like) in any cardiac signal (both abnormal as well as normal) is still in a developing stage. Existing methods have used the concept of sharpness (for example to detect R-waves) but have had limited success. This is due in part to the overly simplistic mathematical treatment this concept has received, as reflected in the rudimentary algorithms used for these measurements. Most of the current detection methods rely on three point interpolations to measure sharpness, may produce inaccurate estimates, if waveforms are complex or are contaminated with noise.

General System Overview

The present subject matter provides, among other things, a system of classifying a cardiac signal by computing a curvature versus time signal from a sensed cardiac signal and comparing the computed curvature versus time signal with a set of predetermined templates. The present system also provides an automated identification and classification of peaks, knees, inflection points, and the like in cardiac signals that takes into account wave scale and complexity that can yield a more accurate classification of cardiac signals.

The first step in the process includes computing continuously a curvature versus time signal from a sensed cardiac signal on a real-time basis. The process also includes extracting features (features are generally significant points of interest on the sensed cardiac signal) continuously on a real-time basis from the computed curvature versus time signal. Next, the process includes continuously separating a set of features associated with a first complex upon detecting a second subsequent complex so that each individual complex can be identified and classified on a real-time basis. Then the process includes aligning and classifying the extracted and separated set of features by comparing the separated set of features with a set of predetermined templates. Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

Referring now to Figure 1, there is one embodiment of the first step in the process of sensing a cardiac signal 100 according to the present invention. Shown in Figure 1 are detection of heart beats associated with first and second complexes 110 and 120 at times ' t_1 ' and ' t_2 ' associated with the sensed cardiac signal 100 on a real-time basis on a time line 130. Also, shown on the time line 130 are the various sample points X_1 , X_2 , X_3 , X_I used in computing a curvature versus time signal on the first complex 110. In the example embodiment shown in Figure 1, the sample points can be some fixed interval of time, such as 2, 4, 6... milliseconds, at which curvatures are computed on the sensed cardiac signal. Also shown in this embodiment, is the detection of the complexes (110, 120, and so on) on a continuous basis on the sensed cardiac signal 100.

Referring now to Figure 2, there is shown one embodiment of generating a curvature versus time signal 200 on a real-time basis derived from the sensed cardiac signal

100 shown in Figure 1 according to the present invention. Figure 2 is also on the same time line 130 as in Figure 1. Curvature figure 200 shown in Figure 2 is a computed curvature (expressed in time) versus time signal generated continuously by computing curvatures at the sample points $X_1, X_2, X_3, \dots, X_I$ on the sensed cardiac signal 100 shown in Figure 1.

5 Curvature figures 210 and 220 are computed curvature versus time signals associated with first and second complexes 110 and 120 shown in Figure 1, respectively. In this example embodiment, the curvature versus time signal is computed by overcoming the dimensionality of the curvature by changing the dimensionality of the curvature to time. The reason for overcoming the dimensionality of the curvature is to convert the time versus voltage signal, which is time versus curvature, to a time versus time signal to facilitate easier computation of curvature (for example, when a curve exists in length-length space, the quantity has dimension of length and is traditionally called the radius of curvature, and if the curve exists in time-time space, the analogous quantity will be called the radius of time). In this time-time space the curvature has a dimension of 1/Time. Also, shown in 10 Figure 2 are some example sample points 230 at which curvatures are computed.

Referring now to Figures 3A and 3B, there is shown one example embodiment of extracting and aligning 300 sets of features associated with respective detected complexes. Figure 3A, illustrates continuously extracting features 320 from the computed curvature versus time signal 200 shown in Figure 2. Also shown in this example embodiment, are 15 some sample times in milliseconds 330 when the extracted features occur on the time line 130. Figure 3A is also on the same time as that of Figures 1 and 2. In the example embodiment shown in Figure 3A, the sample times (where the curvatures are computed) have a fixed interval of 2 milliseconds. Also, in this example embodiment, the beat associated with first complex 110 is detected at 11 milliseconds (t_1) and the beat associated with the second subsequent complex 120 is detected at 101 milliseconds (t_2). 20

Figure 3B shows separating sets of extracted features 310 associated with the complexes 110, 120 ... on a continuous basis from the continuously extracted features 320 shown in Figure 3A. In the example embodiment shown in Figure 3B, a set of features 340 associated with first complex is separated upon detecting the second subsequent complex 120. Also shown are separating a set of features 350 associated with second complex upon 25 30

detecting a third subsequent complex. This process of separating a set of features associated with a complex is done on a continuous basis. Features associated with first complex is separated from the features of subsequent second complex in order to (so that the features are not mingled with the extracted features of the second subsequent complex) classify the sensed first complex 110. The next step is to identify fiducial features 360, 370, and so on. In the example embodiment shown in Figure 3B, fiducial feature 360 is identified based on comparing times when the separated sets of extracted features associated with the first complex 110 occur with a time when the heart beat associated with the first complex 110 is detected (t_l'), and choosing a feature from the set of features 340 that is closest in time to the time when the heart beat associated with the first complex 110 is detected. In the example shown in Figure 1, the first complex 110 is detected at 11 milliseconds. The times when the separated set of features 340 associated with the first complex 110 occur are 2, 4, 8, 10, 12, 14, 20, and 24 milliseconds as shown in Figure 3A. Based on comparing the times when the separated set of features 340 occur with the time when first complex 110 was detected, the feature 360 that occurs at a time of 10 milliseconds is the closest in time to the detected first complex 110 which occurs at 11 milliseconds. Therefore, extracted feature 360 is selected as the fiducial feature from the separated set of features 340 associated with the first complex 110. Similarly, the extracted feature 370 is selected as the fiducial feature for the separated set of features 350 associated with subsequent second complex 120. This process repeats itself continuously on a real time basis. In some embodiments, the fiducial feature is identified from the set of separated features associated with the first complex based on a predetermined deviation value. The predetermined deviation value is based on a sample point having an amplitude farthest from a predetermined reference point.

The next step is to align the separated set of features 340 associated with the first complex 110, and to classify the separated set of features 340 by comparing the aligned set of features with a set of templates. Separated sets of features 340 and 350 are aligned to normalize the separated sets of feature 340 and 350 so that the aligned features aid in comparing the separated sets of features with a template to classify the sensed complexes 110 and 120. Figure 3B, illustrates one example embodiment of aligning the set of

extracted features 340 (associated with first complex 110) with respect to an identified fiducial feature 360. In this example embodiment, the time when the identified fiducial feature occurs (at 10 milliseconds) is subtracted from each of the times when the separated set of features 340 associated with the first complex 110 occurs (at 2, 4, 8, 10, ... milliseconds) to arrive at aligned times -8, -6, -2, 0, 2, 4, 10, and 14 milliseconds for the separated set of features 340. Similarly, the aligned times -8, -2, 0, 2, 4, and 10 are computed for the separated set of features 350 associated with the second complex 120. This process of aligning separated set of features continues on a real time basis for the detected complexes on the sensed cardiac signal 100. It can be seen from the above illustrated computation, that the process aligning helps normalize the times associated with each of the separated sets of features, and how it aids in comparing the separated set of features 340 and 350 with a set of templates and in classifying the sensed complexes 110 and 120.

Figure 4, illustrates a method 400 of identifying and classifying a sensed cardiac signal on a real-time basis. Method 400, as shown in Figure 4, begins with step 410 by sensing a cardiac signal 410 from the one or more electrodes disposed in or around a heart 515 on a continuous basis.

The next step 420 in the process comprises computing curvatures at sample points $X_1, X_2, X_3, \dots, X_I$ on the sensed cardiac signal. In some embodiments, the sample points $X_1, X_2, X_3, \dots, X_I$ are fixed intervals of time at which the sensed cardiac signal is computed for its curvature. The sensed cardiac signal can be an atrial or ventricular signal of a heart. In one embodiment, the curvatures at sample point $X_1, X_2, X_3, \dots, X_I$ is computed by fitting a cubic least square error curve to the sensed cardiac signal by using N sample points. In this embodiment, N is an odd number greater than or equal to 5. Also in this embodiment, the cardiac rhythm management system computes the curvature at a mid point of the N sample points. In one embodiment, the cardiac rhythm management system computes curvature (K) at a sample point X_i on the cardiac signal by using 5 sample points over which the cubic fit is (N being 5 in this example) made using

$$K = (2C_i / (1 + B_i^2)^{3/2})$$

where

$$B_I = T_1 Y(I-2) + T_2 Y(I-1) + T_3 Y(I) + T_4 Y(I+1) + T_5 Y(I+2)$$

$$C_I = S_1 Y(I-2) + S_2 Y(I-1) + S_3 Y(I) + S_4 Y(I+1) + S_5 Y(I+2)$$

where $S_1, S_2, S_3 \dots$ and $T_1, T_2, T_3 \dots$ are constant terms in the summation. In this embodiment, I corresponds to the sample point at which the curvature is being computed. For example, if the sample point is X_3 , then I will be equal to 3 and so on.

In another embodiment, the system computes average curvature between two adjacent sample points by using a linear interpolation of the B_I and C_I between the two adjacent sample points (this is done by doing the integral of the curvature between the two adjacent sample points). This integration helps capture any curvatures that become larger between the two adjacent sample points, so that the point-wise curvature values may more robustly represent the curvatures in the sensed cardiac signal. The system also integrates curvature versus time curve to find the area under the curve. This area under the curve represent the total change in angle between two points on the original cardiac signal. Thus, peaks, turns, inflections, and the like in the cardiac signals can be identified when the curvature versus time curve has peaks or nadirs. These peaks and nadirs denote points along the sensed cardiac signal where the turns are locally sharpest. Also, slow but steady turns on the sensed cardiac signal can be characterized by a small peak having a substantial area under the curvature curve. Thus, integrating curvatures between two adjacent sample points can help capture any curvatures that may become larger between any two adjacent sample points.

In one embodiment, the cardiac rhythm management system computes curvatures at sample points $X_1, X_2, X_3, \dots, X_I$ on the sensed cardiac signal on a continuous basis.

Then the next step 430 in the process includes extracting features from the computed curvatures by comparing the computed curvatures with a set of predetermined threshold values. Figure 3A, illustrates extracting features from the computed curvatures at the sample points $X_1, X_2, X_3, \dots, X_I$. In some embodiments, the set of predetermined threshold values are based on a previous curvature value, a first curvature value, and a curvature threshold limit. In one embodiment, the step of extracting features from the curvature versus time signal is done on a continuous basis on the sensed cardiac signal as

shown in Figure 3A. In some embodiments, the features are defined by one or more metrics. In this embodiment, the one or more metrics are defined as area under a computed curvature, a time of centroid of the area, and a value of original signal amplitude at a time of centroid of the area associated with the feature.

5 Then the next step 440 comprises separating a set of features associated with a first complex upon detecting a second subsequent complex from the sensed cardiac signal. Separating of extracted features associated with the detected complex is illustrated in detail Figures 1, 2, 3A and 3B. In some embodiments, the second subsequent complex is detected based on continuously processing the sensed cardiac signal to produce a signal that is the
10 absolute value of the first derivative of a sensed cardiac signal versus time. Then comparing the produced absolute value versus time signal with a predetermined decaying threshold value to detect an occurrence of the second subsequent complex. In some other embodiments, the second subsequent complex is detected when the absolute value of the first derivative exceeds a predetermined decaying threshold value. In some embodiments,
15 the features associated with the first complex are stored in a memory until the second subsequent complex is detected, and at that point, the features associated with the first complex are replaced by the features associated with the second subsequent complex in the memory. The step of separating can comprise separating the set of features based on selecting features associated with the first complex having a predetermined time earlier
20 than the detected second subsequent complex. In some embodiments, each of the set of features are further compared to an area threshold value to eliminate features less than the area threshold value. This can result in a set of revised features that can represent the first complex.

Then the next step 450 in the process is to identify a fiducial feature from the set
25 of separated features associated with the first complex based on a predetermined deviation value. In some embodiments, fiducial feature is identified based on comparing the time when the first complex occurs with the times when the separated set of features associated with the first complex occur. The process of identifying a fiducial feature is discussed in more detail with respect to Figures 3A and 3B.

Then the next step 460 in the process comprises aligning the set of separated features with respect to the identified fiducial feature. The process of aligning is also discussed in more detail in Figure 3B. The process of aligning helps normalize the times associated with each of the separated set of features and further facilitates in comparing the separated set of features with a set of predetermined templates to classify the detected complex.

Then the next step 470 comprises comparing the aligned set of separated features with a set of predetermined templates. In one embodiment, the set of predetermined templates are one or more known types of heart beat signals. In another embodiment, the set of predetermined templates consists of sets of template boxes or zones for each of the known types of heart beat signals. Generally, each template box or zone can have center amplitude, a time width, and an amplitude width. Also generally, the template boxes or zones for each known type of heart beat can consist of one or more template boxes or zones each of which can have different centers and widths. In this embodiment, the comparing step comprises assigning a score based on how well each feature matches with each of the set of template boxes or zones. In this embodiment, if the separated set of features associated with the first complex fails to match with the set of templates then the complex is assigned with an unknown heart beat classification. In one embodiment, the set of template boxes or zones are modified over time to reflect any changes in sets of separated features used in matching with the template boxes or zones. This can permit known beat type templates to follow slow trends or long-term changes in the cardiac signal.

The next step 480 in the process comprises classifying the detected first complex based on the outcome of the comparison. Then the next step 490 comprises providing a therapy based on the outcome of the classification. In one embodiment, the next step includes guiding a therapy to a heart based on the outcome of the classification. In another embodiment, the next step in the process includes storing classifications for future diagnostic purposes.

Figure 5, is a schematic/block diagram 500 illustrating one embodiment of portions of a cardiac rhythm management system 505, which is coupled to a heart 515. Cardiac rhythm management system 505 includes a power source 580, a controller 540, a sensing

circuit 520, a therapy circuit 590, and a via node/bus 530. The sensing circuit 520 is coupled by a lead 510 to the heart 515 for receiving, sensing, and or detecting electrical heart signals. The sensing circuit 520 provides one or more sensed cardiac signals to the controller 540, via the node/bus 530. The controller 540 also controls the delivery of a therapy provided by the therapy circuit 590 and/or other circuits, as discussed below.

The controller 540 includes various modules, which are implemented either in hardware or as one or more sequences of steps carried out on a microprocessor or other controller. Such modules are illustrated separately for conceptual clarity; it is understood that the various modules of the controller 540 need not be separately embodied, but may be combined and/or otherwise implemented, such as in software/firmware.

In general terms, the sensing circuit 520 senses a cardiac signal on a continuous basis from a heart tissue in contact with a catheter lead 510 to which the sensing circuit 520 is coupled. In one embodiment, the sensed cardiac signal is an atrial signal. In another embodiment, the sensed cardiac signal is a ventricular signal. Sensed cardiac signal from the sensing circuit 520 is then received and processed by an analyzer 550 of the controller 540 to compute curvatures continuously on a real-time basis at sample point $X_1, X_2, X_3, \dots, X_i$ on the sensed cardiac signal. In some embodiments, the sample points are spaced at fixed intervals of time preset by the analyzer 550 on the sensed cardiac signal. In one embodiment, the analyzer 550 computes curvature at sample points $X_1, X_2, X_3, \dots, X_i$ by fitting a cubic least square error curve to the sensed cardiac signal using N sample points to fit the cubic least square error curve. In one embodiment, the analyzer 550 computes the computing curvature (K) at a sample point X_i on the cardiac signal when using 5 sample points over which the cubic fit is (N being 5 in this example) made using

$$K = (2C_i / (1 + B_i^2)^{3/2})$$

where

$$B_i = T_1 Y(I-2) + T_2 Y(I-1) + T_3 Y(I) + T_4 Y(I+1) + T_5 Y(I+2)$$

$$C_i = S_1 Y(I-2) + S_2 Y(I-1) + S_3 Y(I) + S_4 Y(I+1) + S_5 Y(I+2)$$

where $S_1, S_2, S_3 \dots$ and $T_1, T_2, T_3 \dots$ are constant terms in the summation. In this example embodiment, I is equal to the point at which the curvature is being computed. For example,

if the curvature is being computed at sample point X_3 , then I will be equal to 3 and so on. In one embodiment, N is an odd number greater than or equal to 5. In this embodiment, the analyzer 550 computes curvature at a midpoint of the N number of sample points.

In another embodiment, the analyzer 550 computes curvature based on an average curvature between two adjacent sample points based on a linear interpolation of the B_i and C_i between two adjacent points (integrating the computed curvatures between the two adjacent sample points). In one embodiment, the analyzer 550 computes the curvatures continuously on a real-time basis from the sensed cardiac signal. Then the analyzer 550 extracts features by comparing the computed curvatures to a set of predetermined threshold values. In one embodiment, the predetermined threshold values are based on a previous curvature value, a curvature value, and a curvature threshold limit. In one embodiment, the analyzer 550 extracts features on a continuous basis. Then the analyzer 550 separates a set of features associated with a first complex upon detecting a second subsequent complex from the sensed cardiac signal. Then the analyzer 550 identifies a fiducial feature from the set of separated features associated with the first complex based on a predetermined deviation value. Then the analyzer 550 further aligns the set of separated features with respect to the identified fiducial feature. In one embodiment, the analyzer 550 separates the set of features associated with the first complex based on a predetermined time earlier than the detected second subsequent complex. In one embodiment, the predetermined deviation value is based on a sample point having an amplitude farthest from a predetermined reference point.

Then a comparator 570 coupled to the analyzer 550, compares the aligned set of features associated with the first complex with a predetermined set of templates, and classifies the first complex based on the outcome of the comparison. In one embodiment, the comparator 570 issues a command signal based on the outcome of the classification. In another embodiment, the therapy circuit 590 coupled to the comparator 570 delivers the electrical energy through the lead 510 to at least one electrode disposed in or around the heart 515 upon receiving the command signal from the comparator 570. The electrical energy delivered by the therapy circuit 590 can be a pacing pulse electrical energy. In one embodiment, the analyzer 550 includes a variable gain circuitry that can adapt according

to the changes in the sensed cardiac signal. In one embodiment, the controller 540 includes a memory 560 coupled to the comparator 570 and the analyzer 550 to store the extracted features of the first complex. In another embodiment, the memory 560 stores the classified first complexes for diagnostic purposes.

5 It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

10

Conclusion

The above described method provides, among other things, a curvature based complex identification and classification. The process comprises sensing a cardiac signal and computing curvatures at sample points on the sensed cardiac signal, and then to extract
15 features from the computed curvatures. Then to compare the extracted features with a set of predetermined templates, and then to classify the cardiac signal based on the outcome of the comparison.

WHAT IS CLAIMED IS:

1. A method, comprising:
sensing a cardiac signal;
5 computing curvatures at sample points $X_1, X_2, X_3, \dots, X_I$ on the sensed cardiac signal;
extracting features from the computed curvatures;
comparing the extracted features with a set of predetermined templates; and
classifying the cardiac signal based on an outcome of the comparison.
10
2. The method of claim 1, wherein the cardiac signal comprises sensing complexes in real time, wherein the complexes are cardiac cycles.
3. The method of claim 2, wherein computing the curvatures at sample points $X_1, X_2, X_3, \dots, X_I$ comprises computing curvatures at the sample points $X_1, X_2, X_3, \dots, X_I$ by
15 fitting a cubic least square error curve to sensed complexes on the cardiac signal, wherein the sample points have a predetermined interval of time between adjacent sample points.
4. The method of claim 3, wherein computing the curvatures at sample points $X_1, X_2, X_3, \dots, X_I$ comprises fitting a cubic least square error curve around a sample point by
20 using N number of sample points to fit the cubic least square error curve, wherein N is an odd number greater than or equal to 5.
5. The method of claim 4, wherein computing the curvature at the sample point using
25 the N number of sample points comprises using the sample point as a mid point of the N number of sample points.
6. The method of claim 5, wherein computing the curvature (K) at a sample point X_I of the cardiac signal when using 5 sample points to fit the cubic least square error curve,
30 is based on

$$K = (2C_I / (1 + B_I^2)^{3/2})$$

where

$$B_I = T_1 Y(I-2) + T_2 Y(I-1) + T_3 Y(I) + T_4 Y(I+1) + T_5 Y(I+2)$$

$$5 \quad C_I = S_1 Y(I-2) + S_2 Y(I-1) + S_3 Y(I) + S_4 Y(I+1) + S_5 Y(I+2)$$

where S and T are constants.

7. The method of claim 6, wherein computing the curvature comprises computing an average curvature between two adjacent sample points based on a linear interpolation of
10 the B_I and C_I between two adjacent points and integrating the computed curvatures between the two adjacent sample points $X_1, X_2, X_3, \dots, X_I$.

8. The method of claim 3, wherein extracting the features further comprises:
extracting features from the computed curvatures is based on comparing the
15 computed curvatures to a set of predetermined threshold values; and
identifying and separating a set of extracted features associated with the first complex upon detecting a second subsequent complex from the sensed cardiac signal.

9. The method of claim 8, wherein the set of predetermined threshold values are based
20 on a previous curvature value, a first curvature value, and a curvature threshold limit.

10. The method of claim 9, wherein separating the set of extracted features comprises separating the set of features based on identifying features associated with the first complex having a predetermined time earlier than the detected second subsequent complex.

25 11. The method of claim 8, wherein comparing the extracted features comprises comparing the separated set of extracted features associated with the first complex with a set of predetermined templates.

12. The method of claim 11, wherein comparing the extracted features further comprises:
 - identifying a fiducial feature from the set of separated features associated with the first complex based on a predetermined deviation value; and
 - 5 aligning the set of separated features associated using the identified fiducial feature.
13. The method of claim 12, wherein the predetermined deviation value is based on a sample point having an amplitude farthest from a predetermined reference point.
- 10 14. The method of claim 13, further includes repeating the above steps for a real-time classification of heart beat signals from the sensed cardiac signal.
15. The method of claim 13, wherein the feature is defined by one or more metrics.
- 15 16. The method of claim 15, wherein the one or more metrics are area under a computed curvature, a time of centroid of the area, and a value of original signal amplitude at a time of the centroid of the area.
17. The method of claim 13, wherein comparing the set of features comprises
- 20 comparing the set of features associated with the first complex with one or more predetermined heart beat signals.
18. The method of claim 8, wherein the predetermined set of templates comprises one or more predetermined template zones defined by a center time, a center amplitude, a time
- 25 width, and an amplitude width.
19. The method of claim 1, further comprises providing a therapy to a heart based on the outcome of the classification.

20. The method of claim 1, further comprises guiding a therapy to a heart based on the outcome of the classification.

21. The method of claim 1, further comprises storing classifications for diagnostic purposes.

22. The method of claim 1, wherein computing the curvature further comprises permitting the computed curvature signal to have a variable gain that adapts according to the changes in sensed cardiac signal.

10

23. A cardiac rhythm management system, comprising:

at least one electrode;

a signal sensing circuit coupled to the electrode to sense a cardiac signal;

15 a controller coupled to the sensing circuit, wherein the controller receives the sensed cardiac signal, and wherein the controller includes:

an analyzer, to compute curvatures at sample points $X_1, X_2, X_3, \dots, X_I$ on the sensed cardiac signal, wherein the analyzer extracts features by comparing the computed curvatures to a set of predetermined threshold values; and

20 a comparator, coupled to the analyzer, compares the extracted features with a set of predetermined templates, and classifies the sensed cardiac signal based on the outcome of the comparison.

24. The system of claim 23, wherein the sensing the cardiac signal includes sensing complexes on a real-time basis, wherein the complexes comprise heart beat signals.

25

25. The system of claim 23, wherein computing curvatures comprises computing curvatures at the sample points $X_1, X_2, X_3, \dots, X_I$ by fitting a cubic least square error curve to a first complex of the sensed cardiac signal using an N sample points to fit the cubic least square error curve, wherein the analyzer extracts features of the first complex
30 by comparing the computed curvatures of the first complex to a set of predetermined

threshold values, and wherein the analyzer further separates a set of features associated with the first complex upon detecting a second subsequent complex from the sensed cardiac signal; and wherein the comparator compares the aligned set of features associated with the second subsequent complex with a set of predetermined templates, and classifies the first
5 complex based on the outcome of the comparison.

26. The system of claim 25, wherein the comparator issues a command signal based on the outcome of the classification.

10 27. The system of claim 26, further comprises a therapy circuit, coupled to the comparator, to deliver electrical energy through the at least one electrode upon receiving the command signal from the comparator.

15 28. The system of claim 27, wherein the electrical energy is a pacing pulse electrical energy.

29. The system of claim 25, wherein the set of predetermined threshold values are based on a previous curvature value, a curvature value, and a curvature threshold limit.

20 30. The system of claim 25, wherein the analyzer further identifies a fiducial feature from the set of separated features associated with the first complex based on a predetermined deviation value, and further aligns the set of separated features associated with the first complex with respect to the identified fiducial feature.

25 31. The system of claim 30, wherein the analyzer separates the set of features associated with a first complex based on a predetermined time earlier than the detected second subsequent complex.

30 32. The system of claim 31, wherein the predetermined deviation value is based on a sample point having an amplitude farthest from a predetermined reference point.

33. The system of claim 25, wherein N is an odd number greater than or equal to 5.

34. The system of claim 33, wherein the computing curvature comprises computing curvature at a mid point of the N number of sample points.

5

35. The system of claim 34, wherein the analyzer computes the curvature (K) at a sample point X_i on the cardiac signal when using 5 sample points to fit the cubic least square error curve, based on

10
$$K = (2C_i / (1 + B_i^2)^{3/2})$$

where

$$B_i = T_1 Y(I-2) + T_2 Y(I-1) + T_3 Y(I) + T_4 Y(I+1) + T_5 Y(I+2)$$

$$C_i = S_1 Y(I-2) + S_2 Y(I-1) + S_3 Y(I) + S_4 Y(I+1) + S_5 Y(I+2)$$

where S and T are constants.

15

36. The system of claim 35, wherein the analyzer computes an average curvature between two adjacent sample points based on linear interpolation of the B_i and C_i between two adjacent points and integrating the computed curvatures between the two adjacent sample points.

20

37. The system of claim 25, wherein the analyzer further comprises a variable gain, wherein the variable gain adapts according to changes in the sensed cardiac signal.

38. The system of claim 25, wherein the at least one electrode is disposed in or around
25 a heart.

39. The system of claim 25, further comprises a memory to store the extracted features of the first complex.

**CURVATURE BASED METHOD FOR SELECTING FEATURES FROM AN
ELCTROPHYSIOLOGIC SIGNALS FOR PURPOSE OF COMPLEX
IDENTIFICATION AND CLASSIFICATION**

5

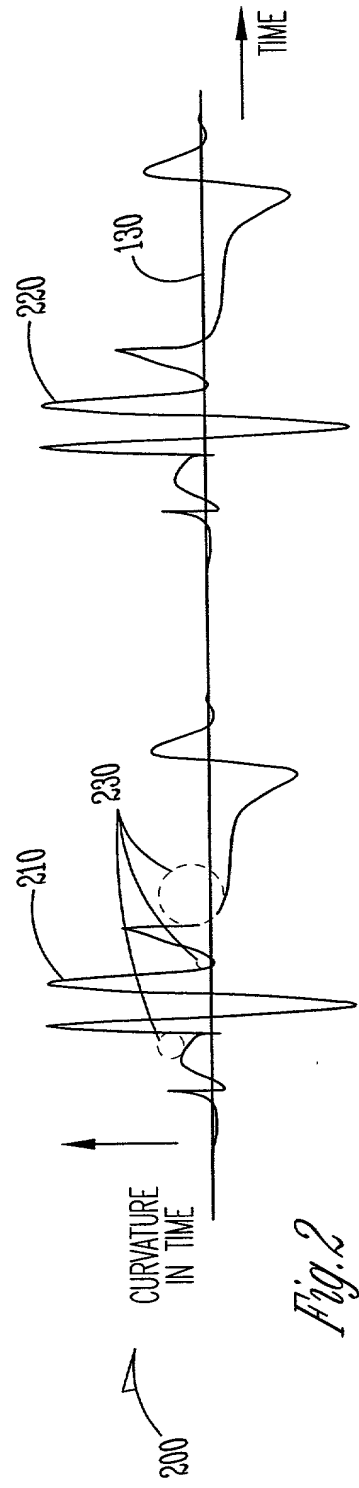
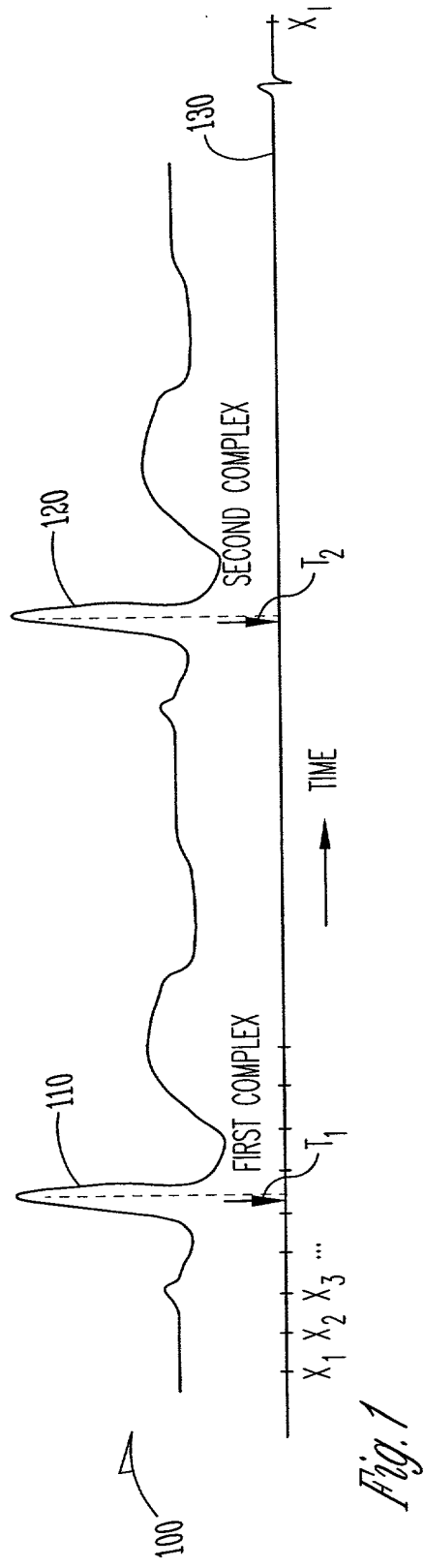
Abstract of the Disclosure

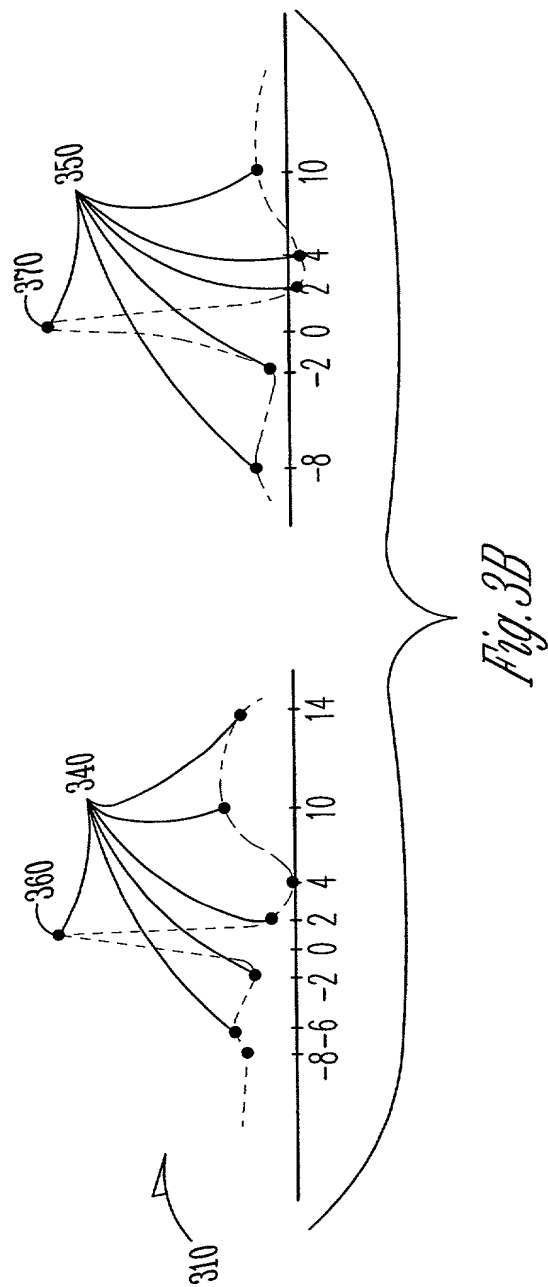
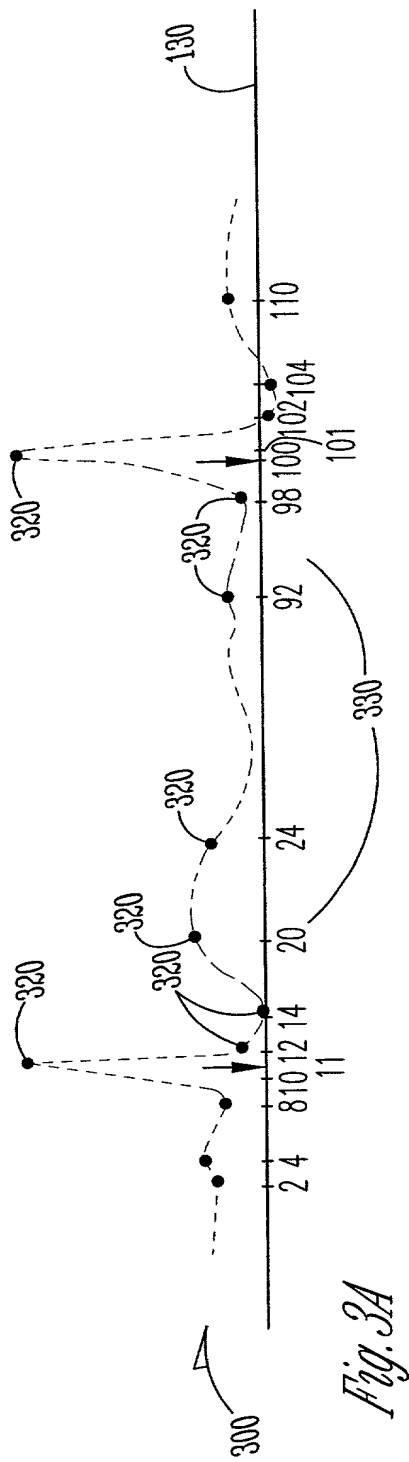
A method for curvature based complex identification and classification comprises sensing a cardiac signal and computing curvatures at sample points on the sensed cardiac signal. Then to extract features from the computed curvatures, and compare the extracted
10 features with a set of predetermined templates, and then to classify the sensed cardiac signal based on the outcome of the comparison.

"Express Mail" mailing label number: EL709304003US

Date of Deposit: October 31, 2000

This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to the Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.





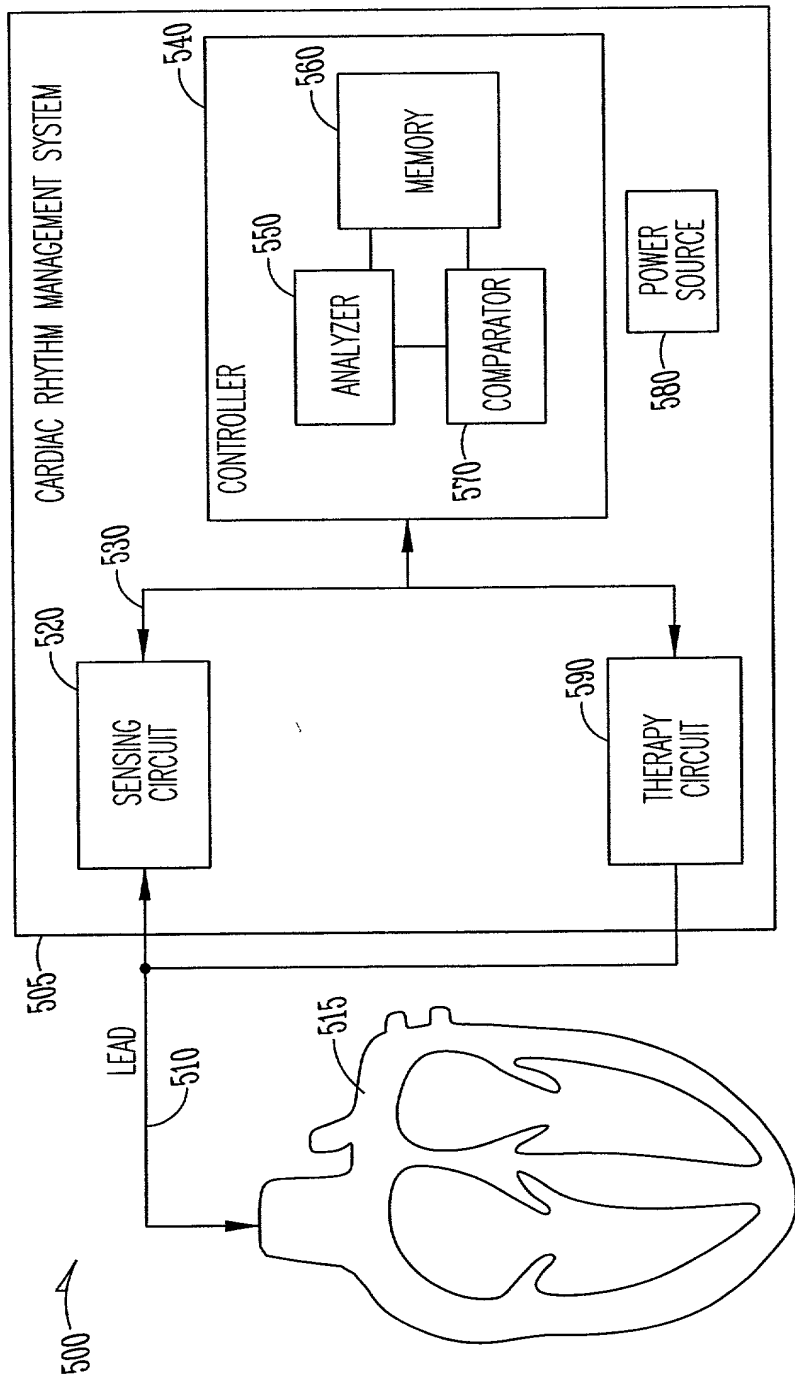


Fig. 5

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **CURVATURE BASED METHOD FOR SELECTING FEATURES FROM AN ELECTROPHYSIOLOGIC SIGNALS FOR PURPOSE OF COMPLEX IDENTIFICATION AND CLASSIFICATION.**

The specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

No such claim for priority is being made at this time.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Anglin, J. Michael	Reg. No. 24,916	Hill, Stanley K.	Reg. No. 37,548	Nasiedlak, Tyler L.	Reg. No. 40,099
Beekman, Marvin L.	Reg. No. 38,377	Huebsch, Joseph C.	Reg. No. 42,673	Nelson, Albin J.	Reg. No. 28,650
Bianchi, Timothy E.	Reg. No. 39,610	Jurkovich, Patti J.	Reg. No. 44,813	Nielsen, Walter W.	Reg. No. 25,539
Billion, Richard E.	Reg. No. 32,836	Kalis, Janal M.	Reg. No. 37,650	Oh, Allen J.	Reg. No. 42,047
Black, David W.	Reg. No. 42,331	Kaufmann, John D.	Reg. No. 24,017	Padys, Danny J.	Reg. No. 35,635
Brennan, Leoniede M.	Reg. No. 35,832	Klima-Silberg, Catherine I.	Reg. No. 40,052	Parker, J. Kevin	Reg. No. 33,024
Brennan, Thomas F.	Reg. No. 35,075	Kluth, Daniel J.	Reg. No. 32,146	Perdok, Monique M.	Reg. No. 42,989
Brooks, Edward J., III	Reg. No. 40,925	Lacy, Rodney L.	Reg. No. 41,136	Prout, William F.	Reg. No. 33,995
Chu, Dinh C.P.	Reg. No. 41,676	Lemaire, Charles A.	Reg. No. 36,198	Schumm, Sherry W.	Reg. No. 39,422
Clapp, Richard R.	Reg. No. 31,751	LeMoine, Dana B.	Reg. No. 40,062	Schwegman, Micheal L.	Reg. No. 25,816
Clark, Barbara J.	Reg. No. 38,107	Lundberg, Steven W.	Reg. No. 30,568	Scott, John C.	Reg. No. 38,613
Clise, Timothy B.	Reg. No. 40,957	Maeyaert, Paul L.	Reg. No. 40,076	Smith, Michael G.	Reg. No. 45,368
Dahl, John M.	Reg. No. 44,639	Maki, Peter C.	Reg. No. 42,832	Speier, Gary J.	Reg. No. 45,458
Drake, Eduardo E.	Reg. No. 40,594	Malen, Peter L.	Reg. No. 44,894	Steffey, Charles E.	Reg. No. 25,179
Embretson, Janet E.	Reg. No. 39,665	Mates, Robert E.	Reg. No. 35,271	Terry, Kathleen R.	Reg. No. 31,884
Fordenbacher, Paul J.	Reg. No. 42,546	McCrackin, Ann M.	Reg. No. 42,858	Tong, Viet V.	Reg. No. 45,416
Forrest, Bradley A.	Reg. No. 30,837	Moore, Charles L., Jr.	Reg. No. 33,742	Viksins, Ann S.	Reg. No. 37,748
Garnett, Owen J.	Reg. No. 36,143	Nama, Kash	Reg. No. 44,255	Woessner, Warren D.	Reg. No. 30,440
Harris, Robert J.	Reg. No. 37,346				

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:
P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 1 : **Robert J. Sweeney**
Citizenship: **United States of America** Residence: **Woodbury, MN**
Post Office Address: **7853 Cobblestone Road**
Woodbury, MN 55125

Signature: _____ Date: _____
Robert J. Sweeney

Full Name of joint inventor number 2 : **Eric G. Lovett**
Citizenship: **United States of America** Residence: **Roseville, MN**
Post Office Address: **1080 Lovell Avenue**
Roseville, MN 55113

Signature: _____ Date: _____
Eric G. Lovett

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.